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November 25, 2019

Via E-Mail

The Honorable Colm F. Connolly
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street, Unit 31
Room 4124
Wilmington, Delaware 19801

Re: *Pfizer, Inc. et al. v. Aizant Drug Research Solutions Pvt. Ltd.*, CONS C.A. No. 19-743-CFC;
In re: Palbociclib Patent Litigation: C.A. No. 19-md-02912-CFC

Dear Judge Connolly:

I write on behalf of Defendants Dr. Reddy's Laboratories, Aizant, Alembic, Apotex, Aurobindo, Cipla, Hetero, Mylan, Natco, Qilu, Sun, Teva, and Zydus (collectively, "Defendants") regarding a dispute about the contents of the proposed protective order ("Proposed Order") in the above-captioned case. This dispute presents a straightforward question: should Plaintiffs be able to disregard Defendants' critical interest in protecting disclosure of its confidential and trade secret information to competitors (the other defendants) simply so Plaintiffs have the convenience of preparing a smaller number of pleadings, discovery documents, and expert reports. Plaintiffs must not.

Plaintiffs main argument is that: "the parties are on track for 13 separate trials." Nothing can be further from the truth. Defendants do not request it, and agree that there would be no need to seal the courtroom during trial.

However, during discovery, the confidentiality provisions of the Protective Order must be respected. It is common practice in Hatch-Waxman litigations for the plaintiffs to prepare separate filings and other documents shielding one defendant's confidential and trade secret information from other defendants. Here, Plaintiffs offer no reasonable rationale to depart from this established practice other than that it would less work for Plaintiffs to prepare

fewer versions of documents. This is insufficient and Defendants' confidential and trade secret information must be protected to avoid causing competitive harm.

Defendants have requested that the court include in the protective order a provision prohibiting the Plaintiffs from disclosing any one defendant's confidential information to another defendant. In this case, each defendant produced its entire ANDA, which contains trade-secret information about the manufacturing processes for the proposed palbociclib product, and each defendant may further produce documents containing a variety of trade-secret information such as market analysis, marketing plans, commercial suppliers, and contractual relationships with distributors. Good cause exists to include Defendant's proposed provision because the provision is necessary to avoid a substantial risk of competitive harm to the individual defendants resulting from disclosure of sensitive, confidential information to their competitors. *See* Fed.R.Civ.P. 26(c); *Smith v. BIC Corp.*, 869 F.2d 194, 199 (3d Cir. 1989).

Certain types of information are of particular sensitivity and concern, such as processes for manufacturing the active pharmaceutical ingredient, details about ANDA product formulation, and whether a Complete Response Letter from FDA or a response thereto has been issued or submitted. If disclosed to another, competing defendant, these types of information about a defendant can impact both the competing defendant's commercial behavior in the marketplace and strategy in this litigation (such as whether and on what terms to resolve this suit with the Plaintiffs) in ways that cause competitive harm to the defendant whose information was disclosed. Therefore, if such information about one defendant is learned by counsel for another defendant—even outside counsel only—that counsel could not advise his or her client about the case without the risk of causing competitive harm based on possession of the information. Defendants' proposed prohibition on Plaintiffs sharing highly sensitive information with other defendants is necessary to avoid this risk.

Plaintiffs' proposal includes a series of exceptions that essentially negates any protective effect Plaintiffs' proposed provision may have. Plaintiffs ask the Court to permit them to disclose a defendant's sensitive information to all other defendants, including their in-house representatives, in *any* "trial, hearing, pleading, discovery response, deposition, or expert report" that is designated as "Confidential," other than a deposition of another defendant's fact witness. Plaintiffs thus seek the right to divulge a defendant's trade secrets to the defendant's direct competitors whenever it is convenient or

advantageous to do so. Plaintiffs proposal puts the defendants at serious risk of competitive harm from the disclosure of confidential trade secret information to their competitors.

In this case, Plaintiffs have sued 13 separate, unrelated groups of defendants, all of whom are competitors in the field of generic pharmaceuticals and who now seek to compete in the market for generic palbociclib products. Notwithstanding the alignment of Defendants' interests in this case, the Defendants are all competitors with one another whose interests are directly at odds in the marketplace. Indeed, because—unlike Plaintiffs—the Defendants are all new entrants to the market for palbociclib products seeking to market generic products, their competitive positions in the marketplace are in many ways more adversarial with respect to one another than with respect to the Plaintiffs. As a result, it is critical that Defendants' sensitive confidential information be adequately protected from disclosure to their direct competitors, who could use such information to their own benefit and to the detriment of the disclosing defendant.

In an attempt to resolve this dispute without the Court's assistance, Defendants proposed a compromise permitting Plaintiffs to disclose most types of a defendant's confidential information in submissions to the Court, common discovery documents, expert reports concerning validity, and expert depositions without shielding the confidential information from outside counsel for other defendants, but requiring an opportunity to request redaction before documents containing the confidential information could be shared with other defendants' in-house personnel. The proposed compromise required redaction of only certain types of particularly sensitive information (e.g. details about ANDA product formulation or the fact that a Complete Response Letter or a response thereto has been issued or submitted) before documents could be shared with another defendant's outside counsel.

Plaintiffs rejected Defendants' compromise proposal, and suggested that it and Defendant's current proposal would make separate validity trials for each defendant inevitable. Plaintiffs are wrong. Defendants are well aware of the practice in this district to try Hatch-Waxman cases together and Defendants' proposal is expressly subject to the provisions of Paragraph 7 of the proposed Protective Order, which provides that material marked Confidential may be used "to prepare for trial, and to support or oppose any motion or other filing in these Actions, and may be used in testimony at trial, offered into evidence at trial and/or hearings on motions subject to such procedures mandated by the

Court." (Proposed Order at ¶ 7). Under Defendant's proposal, therefore, at trial Plaintiffs would be able to present any admissible evidence they choose, including defendants' confidential information.

Moreover, to the extent that Plaintiffs seek to introduce evidence gathered from one defendant against all defendants collectively, Plaintiffs have already agreed that nothing in the proposed protective order "shall be construed to affect in any way the admissibility of any document, testimony or other evidence at trial." (Proposed Order at ¶ 7). Regardless of the outcome of this dispute, at trial Plaintiffs will have to demonstrate that any evidence submitted against any defendant satisfies the requirements of the Federal Rules of Evidence for admissibility. The Court should not permit Plaintiffs to bypass these obligations in a protective order.

Respectfully submitted,

/s/ Stephen B. Brauerman

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cc: All Counsel of Record